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THE DEVELOPMENT OF A TRI-SERVICE NOTIFICATION SYSTEM FOR TYPE 1 MEDICAL MATERIEL COMPLAINTS

THESIS

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AFIT/GLM/LSM/92S-21

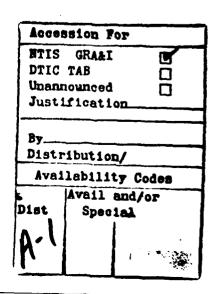
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# THE DEVELOPMENT OF A TRI-SERVICE NOTIFICATION PROCESS FOR TYPE 1 MEDICAL MATERIEL COMPLAINTS

#### THESIS

Presented to the Faculty of the School of Systems and Logistics of the Air Force Institute of Technology

Air University

In Partial Fulfillment of the
Requirements for the Degree of
Master of Science in Logistics Management

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# Preface

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Christopher J. Harrington
Edmund K. Haraguchi

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#### Abstract

The purpose of this study was to investigate the notification process for defective medical material within the Department of Defense. The study first evaluated the efficiency of the current notification processes for defective medical materiel within the Army, Navy, and Air Force. Second, a streamlined notification process and triservice Type 1 message for defective medical materiel was developed. Finally, the effectiveness of this tri-service message was evaluated in comparison to the current notification messages used by the three services. Investigations using observational studies revealed duplication of both function and resources among the medical logistics offices of the three services. Through an iterative interview process, a streamlined notification system and a tri-service Type 1 message was developed. The effectiveness of this proposed tri-service message was investigated through a mail survey of a stratified random sampling of current Type 1 message recipients. Analysis of variance procedures indicate that the proposed tri-service message is effective in communicating information regarding defective medical materiel. Further, respondents indicate that the proposed message format was an acceptable replacement for the current service-specific messages.

# THE DEVELOPMENT OF A TRI-SERVICE NOTIFICATION PROCESS FOR TYPE 1 MEDICAL MATERIEL COMPLAINTS

#### I. Introduction

# Chapter Overview

This chapter discusses the background, current methods, and activities which are involved in the Department of Defense (DoD) notification process for defective medical materiel. The chapter continues with an explanation of the specific purpose of the research. Research and investigative questions posed by the researchers are developed and presented. The chapter concludes with a presentation of the scope of the research and limitations of this study.

#### Background

The term military medical material refers to medical items of supply and equipment for use in Medical Treatment Facilities (MTF) throughout the DoD. Normally these items function properly and assist medical professionals in performing their health care delivery mission. In some instances, however, these items of medical material may be defective and result in the death or serious injury of patients.

In order to communicate information concerning these potentially hazardous items, the DoD has established a notification process for defective medical materiel. We will examine this notification process to determine whether the system may be improved. Several benefits may result from an improved notification process for defective medical materiel. Health care providers may more quickly receive information concerning defective medical materiel. The information they receive may be better understood. Finally, the DoD may save valuable resources such as time, manpower, and money.

Classification of Medical Materiel Complaints. There are hundreds of military MTFs world-wide. This makes the task of distributing information concerning defective medical materiel a monumental one. The Defense Logistics Agency (DLA) is the executive DoD agency responsible for the collection and distribution of information regarding defective military medical materiel. DLA Regulation 4155.28, Reporting and Processing Medical Materiel

Complaints, designates the identification and notification of information pertaining to defective medical materiel as a "medical materiel complaint." Complaints are separated into three categories based upon the item in question and its potential hazard:

Type 1 Complaint - Prescription drugs, reagents,
 biologicals, supplies or equipment which have been

determined by use or test to be harmful or defective such that their use may cause death, injury, or illness to individuals.

- 2. Type 2 Complaint Supplies other than equipment, which are suspected of being harmful, defective, deteriorated, or otherwise unsuitable for use.
- 3. Type 3 Complaint Medical equipment deemed unsatisfactory for use due to malfunction, design, defect, or performance (3:5).

Defense Agencies Involved in the Notification Process.

A variety of DoD activities is involved in the notification process for defective medical material. Familiarity with their roles and responsibilities will serve to enhance understanding of the notification process.

The Defense Medical Standardization Board (DMSB) is a DoD agency subject to the direction, authority, and control of the Assistant Secretary of Defense for Health Affairs. The DMSB is staffed with medical personnel from the Army, Navy, and Air Force. The mission of the DMSB is to improve the medical readiness posture throughout the DoD. They are further charged with conserving resources in exercising the military health care mission. Additionally, the DMSB is responsible for improving the interoperability among the medical departments of the three services. This is accomplished through standardization of medical policy,

procedures, and material in use by the Army, Navy, and Air Force (5:3).

The Defense Personnel Support Center (DPSC) is a DLA activity which serves as the wholesale supplier and item manager for medical material within the DoD. The DPSC staffs a 24-hour Emergency Supply Operations Center to receive and transmit complaints regarding defective medical material.

The Army, Navy, and Air Force medical logistics offices are the United States Army Medical Materiel Agency (USAMMA), the Navy Medical Logistics Command (NMLC), and the Air Force Medical Logistics Office (AFMLO), respectively. These offices conduct wholesale management of medical materiel for the four military services. The NMLC is responsible for wholesale-level medical logistics support to the Marine Corps. The term "tri-service," as it is used throughout this study, refers to actions or coordination among these three service-level medical logistics offices.

Normally, these offices conduct their day-to-day missions independently of one another, separately managing the specific medical logistics functions of their respective services. However, instances arise in which they are required to perform a tri-service mission. An example of such a mission is the determination of components for standardized medical sets, kits, and outfits which are used by the three services. The services' medical logistics

offices are responsible for notifying their respective MTFs concerning items of defective medical material.

The term Medical Treatment Facilities refers to those DoD organizations with a direct health care, health care support, or health care logistics mission. MTFs consist of hospitals, clinics, research laboratories, and other related activities throughout the active and reserve components of the Army, Navy, Air Force, and Marine Corps. These facilities are independently staffed and operated by each service.

MTFs are classified as either fixed or mobile. Fixed MTFs operate in permanent structures and are not subject to deployment. Fixed MTFs are the familiar hospitals and clinics found on most military installations throughout the DoD. Mobile, or contingency, MTFs conduct their missions in movable structures and are subject to deployment. In peacetime, the mission of the these mobile MTFs is to prepare for support of forces in time of conflict. As such, they have limited peacetime direct health care missions. Mobile MTFs do, however, stock significant quantities of medical material related to their wartime mission.

Whether charged with the provision of direct health care, a war preparedness mission, or the provision of health care related services, all MTFs are the receivers of services and information provided by the DPSC, the DMSB, and the wholesale medical logistics offices of each service.

# Processing of Type 1 Complaints

As detailed above, there are three types of medical material complaints: Type 1, for medical material known to cause death or injury; Type 2, for medical supplies, other than equipment, suspected of being unsuitable for use; and Type 3, for medical equipment which has been determined to be unsatisfactory for patient care. Type 1 complaints are the most urgent. They require immediate action because use of the medical material in question may result in a life threatening situation. Type 1 complaints are typically initiated by health care providers at MTFs who discover the defective material. As treatment providers, these individuals are often the first to observe the detrimental effects of defective medical material.

Procedurally, health care providers are required to notify the logistics personnel at the MTF when they suspect an item of medical materiel to be defective. These logistics personnel then contact the Emergency Supply Operations Center of the DPSC. Upon receipt of the complaint, the DPSC then informs an individual at the DMSB, the medical complaint monitor, of the situation. Next, the DMSB complaint monitor will verify the proposed complaint. Verification of the complaint is accomplished through coordination with both the Food and Drug Administration (FDA) and the manufacturer of the product. Verification of the complaint substantiates that the medical item itself is

actually defective, and not its application or particular circumstances of use.

If the complaint is unsubstantiated, the DMSB will contact the DPSC to close the action. The MTF which initiated the proposed complaint will be notified of the materiel's status and the findings of the DMSB.

If the complaint is sustained as a Type 1, the DMSB will notify the DPSC accordingly. The DPSC will then contact the medical logistics offices of the Army, Navy, and Air Force. A single message is sent to the medical logistics offices of the three services. This message contains DPSC directed disposition instructions concerning the defective medical material. Each service receives the same message from the DPSC and must comply with its disposition instructions.

Upon receipt of the disposition instructions from the DPSC, each of the service's medical logistics offices will prepare a subsequent Type 1 message which will be disseminated to the MTFs within their respective services. An example of the Army, Navy, and Air Force Type 1 messages are enclosed in Appendices A, B, and C, respectively. An information flow chart for Type 1 medical material complaints is depicted in Figure 1.

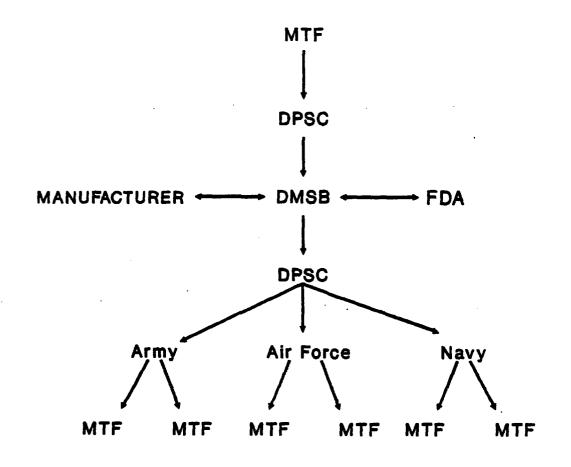


Figure 1. Flow of Information for Type 1 Medical Materiel Complaints

It should be emphasized at this point that the USAMMA, NMLC, and AFLMO independently prepare their own subsequent Type 1 message. These separate messages are prepared from the same "feeder" message received from the DPSC. With the exception of some minor service-specific information, the subsequent messages generated by the Army, Navy, and Air Force medical logistics offices are essentially the same.

They reference the same material complaint, provide the same information to receiving MTFs, and specify the same disposition instructions which were mandated by the feeder message sent to them by the DPSC.

The responsibility for notification of defective medical material rests with the quality control section within each of the services' medical logistics offices.

Consequently, the Army, Navy, and Air Force medical logistics offices each maintain a staff of personnel responsible for the generation of Type 1 messages. The primary function of these individuals is to receive feeder messages from the DPSC, develop subsequent Type 1 messages, and disseminate these messages to their respective service's MTFs.

# Processing of Type 2 and Type 3 Complaints

The flow of information for Type 2 and Type 3 medical materiel complaints are similar. As with Type 1 complaints, health care providers who identify the defective medical materiel will notify the resident logistics personnel at the MTF. These logistics personnel then forward the details of the complaint to the DPSC.

Unlike Type 1 complaints, Type 2 complaints are forwarded directly to the FDA for substantiation. As the nature of Type 2 complaints is not life threatening, as in Type 1 complaints, the substantiation of these complaints

are not as urgent. The FDA conducts investigative research into the nature of the complaint. The manufacturer of the product may be contacted, and efficacy tests may be performed on the material. Upon conclusion of the investigation, the FDA will notify the DPSC of the results.

The system for investigating Type 3 compliants is similar to that of Type 2 complaints. Within the DPSC, the complaint is transferred to the technical device section. In coordination with the manufacturer of the medical equipment, the complaint is verified or unsubstantiated. If verified, the DPSC, in concert with the manufacturer, determines if a specification design change to the equipment is necessary (24:3).

Based on the findings of the FDA (Type 2 complaint), or the equipment manufacturer (Type 3 complaint), the DPSC will either close the complaint as unsubstantiated, or will continue procedures for a substantiated complaint. If the procedure is continued, actions are similar to those of Type 1 complaints. The DPSC will inform the three services' medical logistics offices. As in the Type 1 notification procedure, a single message is sent from the DPSC to each of the service medical logistics offices. Again, this message is received by the quality control section at each of the medical logistics offices. As with Type 1 complaints each service will prepare a subsequent Type 2 or Type 3 message to be disseminated to the MTFs within the respective

services. An information flow chart for Type 2 and Type 3 medical material complaints is depicted in Figure 2.

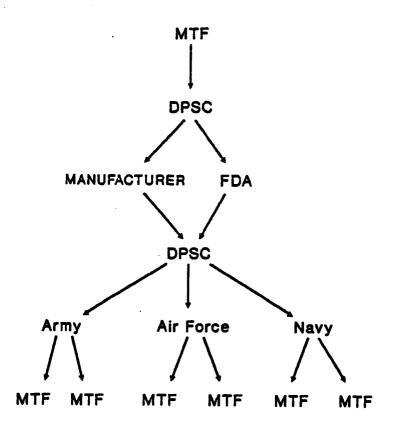


Figure 2. Flow of Information for Type 2 and Type 3 Medical Materiel Complaints

Again, each service independently prepares its own subsequent Type 2 and Type 3 messages based upon the same feeder information received from the DPSC. As with Type 1 messages, the subsequent Type 2 and Type 3 messages

generated by the Army, Navy, and Air Force medical logistics offices are essentially the same.

# The Management Question

In February 1989, the Department of the Army's Director for Health Care Logistics, Colonel Frank Kovach, established a goal for the medical logistics offices of the three services. He challenged the USAMMA, NMLC, and AFMLO to streamline the notification process for defective medical materiel. Colonel Kovach's counterparts in the Air Force and Navy concurred (14:1). Through streamlining the notification process, it was anticipated that information regarding defective medical materiel could be processed more efficiently within the DoD.

It was proposed that a single DoD message for defective medical materiel be developed. It was anticipated that development of such a tri-service message would reduce or eliminate the perceived redundancy and duplication of effort existing in the quality control sections of the three services' medical logistics office.

The development of such an improved system would first require a detailed examination of the entire notification process for defective medical material. Such an examination would focus on the efficiency of the current notification system, to include the identification of resources consumed by the services, and any areas of duplication among the

Army, Navy, and Air Force in the execution of their respective notification functions.

If developed, the single tri-service message for defective medical material proposed by Colonel Kovach must satisfy the requirements of both the services' medical logistics offices which currently generate these messages, and the MTFs for which they are intended. Analysis of the effectiveness of such a tri-service message format must, therefore, be directed at issues at both the service logistics office level and the services' MTFs.

# Purpose of the Study

Although the procedures for reporting and disseminating information concerning defective medical materiel are well established within each service, a comprehensive investigation from the perspective of the DoD has not yet been fully accomplished. As discussed above, it is anticipated that by streamlining the current notification process, improvements in efficiency and effectiveness may be realized. In an improved system, both the logistics personnel who stock and distribute medical material, and the health care providers who utilize these items in the delivery of direct patient care will more rapidly obtain information regarding defective medical material.

Additionally, in establishing a single tri-service message, information may be disseminated utilizing fewer resources

than those consumed by the defective medical materiel notification systems which currently exist in each service.

Therefore, the specific purpose of this study is first to evaluate the efficiency of the current DoD notification process for defective medical material. Once accomplished, the streamlined notification process and single tri-service message for defective medical material requested by Colonel Kovach may be developed. The effectiveness of this tri-service message will then be evaluated with respect to the notification messages for defective medical material currently generated by the medical logistics offices of each service.

In addition to improving the current notification process, the development of a streamlined notification process and a tri-service message may serve as a blueprint for the larger integration of additional wholesale-level medical logistics functions.

#### Research Questions

The management question detailed above lends itself to the development of several research questions which will be explored in this study.

In order to assess the efficiency of the existing service-level process for notification of defective medical material, the first research question was developed:

Research Question One. Is the current service-level notification process for Type 1 medical material complaints efficient?

Specific investigative questions related to this research question are:

- 1. How long does it take the Army, Navy, and Air Force medical logistics offices to prepare and release subsequent messages associated with Type 1 medical materiel complaints?
- 2. What are the personnel resources required by the medical logistics offices of the Army, Navy, and Air Force in the generation of subsequent messages associated with Type 1 medical materiel complaints?
- 3. What equipment is required by the medical logistics offices of the Army, Navy, and Air Force in the generation of subsequent messages associated with Type 1 medical material complaints?

In order to assess the potential for streamlining the notification process for defective medical material among the three services, the second research question was developed:

Research Question Two. How can the existing process for the notification of Type 1 defective medical materiel be streamlined?

Specific investigative questions related to this research question are:

- 1. Can a tri-service notification system for Type 1 complaints be developed in place of the existing notification systems for defective medical material in the Army, Navy, and Air Force medical logistics offices?
- 2. Can a single tri-service message for defective medical materiel be developed for Type 1 complaints which would satisfy the notification requirements of the Army, Navy, and Air Force medical materiel offices?

In order to assess the effectiveness of a single

tri-service message for Type 1 complaints, the third research question was developed:

Research Question Three. Will the single tri-service message for defective medical material be effective in communicating information concerning Type 1 complaints to the medical treatment facilities of the Army, Navy, and Air Force?

Specific investigative questions related to this research question are:

- 1. Is the information contained in the tri-service message for defective medical material for Type 1 complaints clear to all intended Army, Navy, and Air Force recipients?
- 2. Is the information contained in the tri-service message for Type 1 complaints understood by all intended Army, Navy, and Air Force recipients?
- 3. Does the tri-service message provide complete information for Type 1 complaints to all intended Army, Navy, and Air Force recipients?
- 4. Is the format of the tri-service message for Type 1 complaints acceptable to all intended Army, Navy, and Air Force recipients?
- 5. Among intended Army, Navy, and Air Force recipients, how will the effectiveness of the triservice message for Type 1 complaints compare to that of the Type 1 messages currently developed by the logistics offices of each service?
- 6. Among intended Army, Navy, and Air Force recipients, will the proposed tri-service message for Type 1 complaints be acceptable in place of the Type 1 messages currently developed by the logistics offices of each service?

# Research Scope and Limitations

The research contained in this study concerns itself with information and analysis pertaining to Type 1 medical

materiel messages only. Due to the time allotted to conduct this research, processes concerning Type 2 and Type 3 medical materiel complaints were not investigated. For similar reasons, data collection for this research was confined to MTFs and activities within the continental United States. In some instances, it was necessary to collect data from individuals, activities, or ships located outside the continental United States. These actions were necessitated by the fact that the survey populations depicted by these elements were not otherwise represented by elements located within the continental United States.

# Chapter Summary

This introductory chapter discussed the background information concerning the defense organizations and procedures which characterize the DoD defective medical materiel notification process. The classification scheme and reporting procedures for Type 1, Type 2, and Type 3 defective medical materiel complaints were then introduced. Subsequently, the management question which originated this research was presented and the purpose of this study was detailed. Three specific research questions and their associated investigative questions to be answered by this study were then posed by the researchers. The chapter concluded with a discussion of the scope and limitations of the research contained in this study.

Chapter II, Review of the Literature, provides an analysis of the literature pertaining to the notification process within the DoD for defective medical materiel as a component of its medical community's quality control program.

# II Review of the Literature

# Chapter Overview

This review of literature will begin with a discussion of the quality control system as a function of military medical materiel management. The existing DoD notification process for defective medical materiel, as a function of medical quality control, will then be discussed. Literature pertaining to previous efforts to evaluate and integrate the existing notification systems for defective medical materiel within the Army, Navy, and Air Force is then examined. This review will conclude with an examination of an existing DoD notification process for hazardous food and nonprescription drugs.

It must be emphasized that the process being investigated in this research is essentially a military specific one. Although aspects of the defective medical materiel notification process are conducted in other branches of the government and in society at large, the topic as investigated in this literature review is unique to the military departments. The researchers recognized the existence of such industrial notification systems. However, subsequent investigation of civilian industry presented limited application to a strictly military process which is directed and governed by regulations. As a consequence,

this literature review focuses on military notification systems for defective material.

# Medical Quality Control

Effective quality control is recognized as one of the basic functions of medical material management. The Medical Departments of the Army, Navy, and Air Force accomplish this responsibility through a wide variety of internal activities and processes. Examples of these quality control actions within the purview of medical logistics include material inspections, periodic equipment inspections for serviceability and safety, and the surveillance of medical material as it is received, issued, stored, or shipped. The importance of these quality control functions is recognized by the DoD and each of the services. This recognition is evidenced in the regulations which dictate the various missions and govern the specific operations of the USAMMA, NMLC, and AFMLO (6:1; 8:21; 9:44).

Current regulations in the three services describe specific quality control functions to be accomplished at these service-level medical logistics offices. Medical quality control programs such as the drug and pharmaceutical shelf life extension program, disposition instructions for materiel which has been suspended from issue to patients, destruction notifications and procedures for medical materiel which have been determined to be expired or unfit

for use, and serviceability testing of medical materiel are described in explicit detail (7:3; 8:5; 9:15).

These same service regulations direct the three service-level medical logistics offices to establish a process to communicate information concerning defective medical materiel. This process is further directed to transmit information regarding defective medical materiel quality issues to the logisticians and health care providers in each of the services' MTFs (7:16; 8:22; 9:20). Although these quality control functions are the specific responsibility of the Army, Navy, and Air Force medical logistics offices, the medical materiel to which these quality control functions actually apply are largely stored and consumed in the respective services' MTFs. A defective item of medical materiel purchased by the DPSC may be stored in a DLA depot or shipped to any number of the hundreds of MTFs within the DoD.

In such a situation, a communication mechanism must be in place which facilitates the directive that the defective medical materiel "be removed from using activities and serviceable inventories in the Defense Logistics Agency system and suspended from issue" (3:1). Conversely, through application or use, medical materiel may be discovered to be defective at any one of the MTFs within the DoD which uses the materiel. In such a situation a procedure must exist to report the medical materiel which is suspected of being

defective to the respective services' medical logistics office (24:5). In examining this situation, a need to communicate information concerning defective medical material between MTFs, service-level medical logistics offices, and DLA storage activities is apparent.

# Defective Medical Materiel Notification Systems

As a result of the need to communicate this information concerning defective medical materiel, the three services have each developed distinct notification systems for defective medical materiel. An artifact of this process is that separate messages containing the same information are generated by each of the service-level medical logistics offices.

The notification systems for the Army, Navy, and Air Force operate in parallel. The quality control section of each services' medical logistics office receives the same input from the DPSC concerning a defective item of materiel. The services' medical logistics offices each independently validate this message. The information contained in this single feeder message is then reformatted into a service-specific message format. These reformatted messages are then transmitted by the medical logistics offices of the three services to their respective MTFs (24:7). Each of the services uses a unique message format, message processing system, file storage system, and transmission method. In

addition, each of the services separately publishes a periodic medical supply bulletin which contains a "hard copy" of all messages published by the particular service (24:9-10).

The first research question proposed in this study examines the efficiency of the current notification process for defective medical materiel within the DoD. As the Army, Navy, and Air Force notification systems have evolved, an extensive duplication of effort has developed among the services. In interviews with commanders of the USAMMA, NMLC, and AFMLO, it was determined that each of these service-level medical logistics offices employs a dedicated section of personnel to validate, generate, transmit, and file defective medical materiel messages (13:11). In addition, each service employs a staff to edit and publish their respective supply bulletins. Duplicate message databases also exist in each service (24:11).

Examination of the operating reports of the three medical logistics offices reveals that varying efficiencies have been realized among the services in both resource utilization and message processing times (26:7). Previous research by Captain Jack Trakowski, an intern at the USAMMA, indicates that processing times of messages from the medical logistics offices of the three services to their respective MTFs vary by as much as ten days for the same information

(24:9). Hard copy publication of messages in supply bulletins vary by even greater times (26:3).

The second and third research questions proposed in this study relate to examination of the potential streamlining of the existing notification process for defective medical material and the evaluation of the effectiveness of a proposed tri-service message for defective medical material.

Previous research in this area has been limited. A tri-service medical materiel message working group was established in 1989. The streamlining of the existing notification systems, interoperability, and integration of the three services' separate messages have been explored by this group (26:10). The group recognized a strong potential for improvements to be made to the present notification system. They further identified a need for the assessment of the effectiveness of the present system prior to further action (26:10). To date, such an assessment of the current notification process for defective medical material has not been accomplished.

# Hazardous Food and Nonprescription Drug Recall System

In examining the DoD literature for a similar notification process, the recall system for hazardous food and nonprescription drugs provides a striking contrast to

the notification system for defective medical material which was described above.

Hazardous food and nonprescription drugs refer to tampered or suspected tampering of foods or nonprescription drugs, nonprescription medical devices, and health and beauty aids (4:1). As commissaries, exchanges, and other activities stock and distribute these commodities, a notification and recall system has been established by the DoD. Within this notification system, recalls may be initiated by the FDA, the U.S. Department of Agriculture, the U.S. Department of Commerce, or the DPSC (4:1). In accordance with a DMSB policy, the recalls are classified as Class I or Class II. This classification of recalls as Class I or Class II parallels the classification action of defective medical material detailed in Chapter I (5:16-1).

A significant difference exists in the role of the DMSB in this notification system. With respect to the recall of hazardous food and nonprescription drugs, the DMSB does not substantiate or verify the initial complaint. This verification is performed by the government agency, FDA, U.S. Department of Agriculture, or U.S. Department of Commerce, which has initiated the recall. The role of the DMSB in this recall system is only to classify the recall with respect to the actions to be taken within DoD activities.

After the food or nonprescription drug recall has been classified, the DPSC acts as the sole agent for the DoD in coordinating all actions involved in administering the recall. The DPSC formulates a single hazardous food recall message and communicates directly with its Defense depots and Army, Navy, Air Force, and Marine Corps activities potentially affected by the recall (4:3). In addition, the DPSC contacts the base and post exchanges, commissaries, and other retail outlets throughout the DoD which may stock the food or nonprescription drug in question.

Within the recall system established for hazardous food and nonprescription drugs, the role of the service-level medical logistics offices is to provide the DPSC with an address indicator group, or communications address listing, of the MTFs within their respective service (4:4). This address indicator group is used by the DPSC to develop a single DoD listing of message recipients. A single DoD agency, the DPSC, through their Quality Assurance Directorate, performs all of the functions associated with hazardous food and nonprescription drug notification.

In contrast to the notification process and message procedures associated with defective medical material, the notification process for hazardous food and nonprescription drugs presents a streamlined system. A single DoD activity prepares one notification message which is used to communicate the recall of hazardous material to a wide

constituency of defense activities. In contrast to the notification process for defective medical material, the duplication existing among the service-level medical logistics offices is absent in this system of notification. Within the hazardous food recall system, a single database is maintained by the proponent office. In addition, it should be noted that the number of recipients for hazardous food recall messages is significantly greater than the population of MTFs associated with the current messages for defective medical material generated by the three services. The hazardous food and nonprescription drug notification system presents an example of an efficient, streamlined, single message notification system which effectively communicates information concerning defective material.

## Chapter Summary

This chapter presented a review of relevant literature addressing the notification processes for defective medical materiel within the DoD. It reviewed background information concerning quality control as a function of medical materiel management and further introduced a notification system for defective medical materiel as a necessary sub-function of this quality control process. The parallel evolution of the current notification processes within the Army, Navy, and Air Force was discussed. Literature concerning a similar notification process, the hazardous food and nonprescription

drug recall system, was also reviewed. A review of the literature associated with notification systems for defective medical material indicates a demonstrated need for further research, specifically that pertaining to the research questions of this study.

Chapter III, Methodology, presents the research design employed in this study. The various research methods applied, data collection and sampling plans employed, and data analysis procedures used by the researchers are detailed for each research question.

# III. Methodology

# Chapter Overview

This chapter describes the research design used to structure the investigation in order to answer the research questions posed in Chapter I. It constitutes an investigative blueprint, specifying the various research methods to be employed (16:279). In addition, this chapter delineates the relevant population of interest to each research question and subsequently derives a representative sample population for the purpose of survey. A data collection and sampling plan is presented for each research question. Data collection methods and instruments which were developed and employed by the researchers are also discussed. A plan of data analysis is then introduced which details the compilation of data and statistical tests which were employed by the researchers in data analysis. The chapter concludes with a discussion of the assumptions and limitations of the research design used in this study.

# Research Design

The purpose of research design is to detail the various research methods used in this study to collect data concerning the research questions and their associated investigative questions. Due to the distinct nature of the

three research questions posed in the study, a variety of research methods were used.

The specific research questions posed in Chapter I suggest that a time phased sequence of research should be conducted employing these various methodologies. These investigative phases would parallel the three research questions. The first phase would encompass research designed to answer the first research question. The second phase would encompass research designed to answer the second research question, and so forth. Phasing of the research effort will allow information collected from one phase to serve as input to the subsequent phase. In this fashion, the research questions of this study will be answered in turn.

Throughout the investigation, data collection and investigation was accomplished using three research methods: observational study, personal interviewing, and a mail survey. The following is a discussion of the research method used for each research question.

### Research Question One

Is the current service-level notification process for Type 1 medical material complaints efficient?

Operational Definition of Variables. In conducting investigations associated with this research question, the construct of efficiency was operationally defined as the variables of interest associated with processing time,

personnel resources, and equipment required within the Army, Navy, and Air Force medical logistics offices in the generation of their respective Type 1 medical materiel messages. Efficiency was further operationalized by the researchers to include variables of interest concerning the duplication of effort and resources among the service-level medical logistics offices in the generation of their respective Type 1 messages.

Message processing time was operationally defined as the elapsed time required by each service to receive the feeder Type 1 message from DPSC, validate this message, and reformat the information contained in this feeder message into the service-specific Type 1 message format currently required in each notification system for release to the respective MTFs of each service.

Research Method. In answering this research question, it was necessary to physically evaluate the notification system for defective medical materiel which exists in each service. A research method should be selected which would result in the ability to define the system resources used by each service in their respective message generation and notification procedures. Data collection within this method must facilitate the direct comparison of resource utilization between the respective notification systems existing among the three services. An observational study research method was selected by the researchers.

The observational study methodology lends itself to the non-behavioral study required in conducting historical research of defective medical material notification records maintained in each service. Additionally, this method would facilitate investigation of the physical and informational processes and activities used in each service to generate messages for defective material (12:400).

Advantages of the observational study research methodology were numerous. The researchers were able to collect original data concerning message generation at the time it occurred. In addition, observational study allowed the researchers to capture information concerning resource utilization of the entire notification process within each of the services (17:262).

The major disadvantage of the observational study research methodology, as detailed by Emory, is its relatively high cost (12:403). As the observer must be physically present to investigate records and observe process activity, this research method dictates that the researchers travel to the respondent population. This disadvantage was negated by the physical proximity of the medical logistics offices of the three services. These three offices, co-located at Fort Detrick, Maryland, contained the survey population for this investigative question.

Population. The relevant population of interest with respect to this research question is constituted by the quality control sections within each medical logistics office. It is in these Army, Navy, and Air Force quality control sections that the resources, records, and processes associated with medical material message generation are located. These sections are responsible for the generation and transmission of medical material messages.

Sample. As the number of personnel directly involved in the medical material notification process in each service is relatively small, the researchers utilized the entire population as the observational survey sample. Selection of the population as the sample to be observed aids in assuring accuracy. Data precision is increased through both the elimination of systematic variance in selection of a representative sample and in the minimization of the standard error of estimates (12:243).

Instrumentation. The collection of the resource consumption data obtained through observational study was conducted through clustering of like elements for each service and coding of data along the established ratio scales of personnel resources and capital equipment. Collection of message processing elements was conducted using interval scales of elapsed time.

<u>Data Collection Plan</u>. Due to the severe limitations on time and resources, it was impossible to observe the

activities of each of the services' quality control sections over an extended period of time. Therefore, the decision was made by the researchers to conduct continuous measurement observational studies of the notification process for defective medical material within each service for the period of seven days. It was determined by the researchers that this period was sufficient to categorize and collect data concerning the variables of interest associated with resource utilization and to document the physical and informational processes associated with defective medical material notification which occur in each service. Observational studies were conducted on all three activities as they simultaneously processed the same feeder message from DPSC.

The researchers collected specific data concerning the personnel and dedicated material resources required to operate the medical material notification system in each service. In addition, the elapsed time for message processing within each service was directly observed.

In addition to observation of resource utilization in execution of notification procedures and message generation speed, the researchers conducted historical research of notification records for defective medical material maintained in each service. As message processing times are recorded, historical research was conducted for the purpose of establishing a mean message generation time for each

service. A standard six month time period was selected.

This standard period was used by the researchers to conduct a cross-sectional time sampling of the medical material notification messages issued by each service (2:159).

Plan of Data Analysis. Observations of the informational and physical processes involved in each service's notification process were detailed. Evaluation of the respective service's notification processes required a qualitative type of analysis. Informational and physical processes do not neatly lend themselves to mathematical or statistical analysis. Indeed, with respect to the research question involved, statistical analysis of these processes is not the researchers' objective. It is the researchers' objective only to clearly define the notification process in each service and identify any duplication of effort among the services' notification processes.

Comparative analysis of the resource consumption data was conducted by grouping and directly comparing the resource requirements in the quality control sections of the three medical logistics offices. Message processing times were analyzed to determine the average processing time for each service.

### Research Question Two

How can the existing process for the notification of Type 1 defective medical material be streamlined?

Research Method. In answering research question two, it was necessary to examine the requirements of each of the services' respective notification processes. Further, in seeking to satisfy the quality mission of each service, the tri-service notification system for defective medical material designed by the researchers must be acceptable to the medical logistics office of each service. As a consequence of these requirements, the researchers selected the personal interview research method to address this research question.

The personal interview method allows the researcher to gather information from those who are directly involved with the intricacies of the process in question. Personal interviews provide the most effective way to obtain the necessary detail and in-depth explanations of both the process requirements and management controls which would be required for a tri-service notification system (12:320). In conducting personal interviews, the control of interview conditions, ability to gather supplemental information, and quality of information received is far superior to other survey methods (12:320).

Selection of the personal interview methodology provided a further advantage in that it facilitated the development of a proposed tri-service notification procedure for defective medical material through an iterative process conducted over the course of successive interviews. The

researchers were also able to develop a tri-service message for defective medical material and make adjustments to the format and content of this message during ensuing interviews with respondents.

As with the observational study research method, the greatest disadvantage of the personal interview research method, its cost, was muted by the co-location of the interview respondents (12:320).

Population. The relevant population of interest with respect to this research question is again constituted by the personnel from the quality control sections within each medical logistics office. As with the first research question, it is in the quality control sections of medical logistics offices, that the requirements and management controls for the respective notification processes are developed. If a tri-service notification system is to be developed, it must satisfy the service-specific process requirements and management controls which presently exist in each service (26:4).

Sample. In determining the sample population with respect to this research question, a purposive quota sampling technique was selected by the researchers. Using this technique, the researchers selected individual sample members who conformed to specific criteria (12:275). The criteria used by the researchers in their selection process were: (1) Detailed knowledge of the service-specific

requirements of the notification process for defective medical material, and (2) Significant experience in the service-specific notification processes and the exercise of management control over these processes. Proportionally, a single sample member was selected from the Army, Navy, and Air Force. Specifically, the researchers selected the supervisors from each of the service's quality control section.

Data Collection Plan. In addressing the research question, initial personal interview survey questions were largely unstructured and open ended. This lack of structure was deliberate in that it promoted in-depth discussion and elaboration by the respondents concerning their management attitudes toward, and requirements of, a tri-service notification procedure.

Essentially, the researchers were conducting exploratory research in assessing the climate of cooperation which existed in each service concerning the development of a joint defective medical notification procedure. This interrogative method of data collection provided both a cross-check between the service-level logistics offices and added validity to the analysis of observational data collected in investigation of research question one. In addition, this iterative, consensus building method assisted in minimizing the bias of both researchers and respondents in the collection of data.

Through successive interviews a clear identification of the strengths and weaknesses of the existing notification processes within each service was identified. It was anticipated by the researchers that a direct byproduct of the analysis of these interview results would be recommendations for improving the current DoD medical material notification process.

Through analysis of initial interview results, the researchers developed a proposal for a streamlined triservice notification system and an associated single triservice medical material message. Subsequent interviews were more structured. The researchers provided focus to the respondents by asking a standard set of questions concerning the proposed notification process and draft tri-service message. These questions were designed to provide topical direction to respondents, and further, to elicit their comments concerning the critical contents and specifics of the tri-service message format required by each service (12:352).

These questions were tailored to the specific individuals being interviewed and the services that they represented to determine the essential components of a streamlined notification process. In addition, the specific content and format required for each service in the establishment of a single tri-service Type 1 message was

identified. The final, proposed format of the tri-service

Type 1 message is enclosed as Appendix D.

Plan of Data Analysis. In investigation of research question two, an exploratory data analysis approach was used. In this approach, the preliminary data determine the analysis - or a revision of the planned analysis - rather than the analysis presuming to overlay its structure on the data (12:469, 25:2-3). In this instance, the data received from initial interviews was used to formulate a streamlined notification system and single tri-service Type 1 message. The streamlined notification system and tri-service Type 1 message format originally proposed were revised through a process of successive interviews with respondents. The iterative interview process described above contained elements of both data collection and data analysis:

Unlike the typical quantitative investigation, the qualitative research worker sometimes must move back and forth between data sources and ongoing data analysis during the period of data collection. Initial questions are progressively narrowed or, on occasion, shifted entirely as the nature of the living contest becomes apparent through preliminary analysis. (18:91)

### Research Question Three

Will the single tri-service message for defective medical materiel be effective in communicating information concerning Type 1 complaints to the medical treatment facilities of the Army, Navy, and Air Force?

Operational Definition of Variables. In conducting studies associated with this research question the construct

of effectiveness has been operationally defined through recipients' perceptions of the tri-service Type 1 notification message. Specific variables of interest to the researchers within this construct are the clarity, ability to understand, completeness, format, comparison, and acceptability of the tri-service Type 1 message for defective medical material (12:53).

Research Method. In answering this research question it was necessary to evaluate the effectiveness of the triservice message among recipients of the current servicespecific Type 1 notification messages. Only current recipients of the service-specific messages would be able to make valid comparisons with the proposed tri-service message. Due to the geographic dispersion of current Type 1 message recipients, a mail survey research method was selected by the researchers.

selection of this research method suited the investigation of the variables of interest and presented several distinct advantages in the conduct of data collection. Advantages of this research method include its relatively lower cost when surveying a geographically dispersed population, such as that represented in this research question (12:333). Additionally, a mail survey permitted the inclusion of survey respondents, such as those deployed on ships, who would have otherwise been inaccessible. It was further anticipated that the

comparative type of survey questions necessitated by this research question would require more time among recipients than would have been possible with a telephone survey (12:333).

The primary disadvantage associated with a mail survey is the type and amount of information that may be secured (12:333). Survey recipients are limited, with respect to both the questions and the responses available, as they are presented on the survey. A further weakness of the mail survey research method is its reliance on self-reporting by respondents. In addition, the accuracy of mail survey responses has been demonstrated to be related to the respondent's perception of the source of the survey and the degree of anonymity present in survey completion (11:183-184).

Population. In total, the Army, Navy, and Air Force Medical Departments have over three hundred "action" recipients for Type 1 messages (24:7). These recipients are comprised of the MTFs which were detailed in Chapter I. As every Type 1 message generated is received by all of the respective service's MTFs, the relevant population is simply defined as Type 1 message recipients. Though categorized as action recipients, each message may not specifically pertain to every recipient, and thus require action on their part. Action on the part of the recipient is dependent on whether the facility maintains a stock of the materiel in question.

However, the clarity and format of each Type 1 message must be sufficient such that the disposition instructions contained in each message can be read and understood by each recipient should action be required at their particular MTF.

Sample Design. Due to the accuracy of the address indicator groups currently used by each service to address Type 1 messages, the sample frame used by the researchers closely mirrored the relevant population of Type 1 message recipients. Due to considerations of the transit time involved in a mail survey, the sample selected for investigation of this research question consisted of a representative number of all Type 1 message recipients within the continental United States.

The tri-service (Army, Navy, and Air Force), and multicomponent (fixed, mobile, and reserve type facilities)

constituency of the Type 1 message recipient population

dictated that this diverse grouping of subpopulations agree

on the research variables of interest if the proposed triservice message was to be considered acceptable as a

replacement for the three current service-specific Type 1

messages. This led the researchers to choose a stratified

random sampling procedure for selection of the sample to be

used in data collection. In defining population strata, the

researchers sought to maximize the assessment of the

relative agreement (through comparison of subpopulation

means) among the populations with respect to the variables of interest identified above.

The selection of stratified sampling presented several advantages over simple random sampling of the same population. Stratified sampling provided a mean for each stratum as well as a mean for the entire population. As the variability within each stratum is usually less than the variability of the entire population, stratified sampling provides a more accurate estimate of the population mean than does a simple random sampling of the same sample size (19:1133).

The population of Type 1 message recipients was stratified in two ways, by service and by component. The service stratification identified three subpopulations within the population - Army, Navy, and Air Force MTFs. The component stratification also divided the population into three subpopulations - reserve, mobile, and fixed MTFs. This stratification technique facilitated comparison of the mean responses to any particular survey question among the subpopulations of Army, Navy, and Air Force, or among the subpopulations of reserve, mobile, and fixed MTFs.

Selection of a stratified sampling technique provided adequate data for analyzing the survey responses of the various subpopulations and additionally increased the statistical efficiency of the sample. In selecting the particular strata detailed above, the researchers sought to

maximize the differences among strata means and minimize the within-stratum variances for the variables of interest (12:266-267).

Sample Size. A random sample was taken from each subgroup. A 90 percent statistical confidence level was used in this study. The following formula was used to calculate the sample size necessary from each of the population subgroups in order to obtain the desired confidence level:

 $n = [N (Z^2) * P (1 - P)] / [(N - 1) d^2 + Z^2 * P (1 - P)]$ where

n = sample size

N = population size for the respective subgroup

P = maximum sample size factor (.5)

d = desired tolerance (.1)

Z = factor of assurance (1.645) for 90 percent confidence level

The calculated sample size for each of the three service population subgroups was 30 Army, 23 Navy, and 26 Air Force MTFs. The calculated sample size for each of the three component population subgroups was 30 reserve, 19 mobile, and 30 fixed MTFs (10:11-14). Anticipating a response rate of approximately 40 percent, the sample required a total of 199 mail surveys to be distributed to the sample subgroups.

After the sample size of each subgroup was calculated, a controlled procedure utilizing random digits was employed by the researchers to assure that sample members were drawn on a random basis from within each subgroup of the population (22:433-437).

Survey Instrument. A mail survey questionnaire was developed. The intent of this questionnaire was to provide a generalizable measure of the effectiveness of the proposed tri-service type 1 message. Additionally, the survey was to provide information concerning the demographics of the population sample. The completed mail survey questionnaire is enclosed in Appendix E.

Instrument Development. The survey was to developed to evaluate the proposed message's effectiveness as operationalized by its clarity, ease of understanding, format, completeness, comparison to existing service specific messages, and acceptability among the population sample. Survey questions were based on the assessment of indicants tied to these variables of interest within the population. This method of instrument development ensured that the data obtained through the questionnaire could be used to answer the respective investigative questions contained in the research question.

Investigative question one focused on the clarity of the information contained in the proposed tri-service message. Survey questions 1 and 2 were designed to evaluate

this variable of interest within the population. For the purposes of the questionnaire, indicants of clarity were determined to be recipient understanding of intent and required actions.

The second investigative question was directed at assessment of the ease of understanding of the tri-service message by recipients. Survey questions 3 and 11 were constructed to evaluate this variable of interest. Through the indicant of recipient comprehensibility, the researchers sought to determine recipients' ease of understanding of the information contained in the proposed tri-service message.

The third investigative question concerned recipients' perception of message completeness. Survey question 4 was designed to assess if the proposed tri-service message provided the recipient all the information required concerning the defective item of medical material.

The fourth investigative question was directed at the format of the proposed tri-service message. Survey questions 5 and 6, through evaluation of the indicant of respondent recognition of critical message components, were developed to assess this variable of interest.

The fifth investigative question was developed to assess the proposed tri-service message through a comparison to the existing notification message received by the respondent from their respective service. Survey questions 7, 8, and 9 were directed at this research variable of

interest. In the development of these questions, the indicants associated with recipient comparison of message intent, understanding of required actions, and perception of message completeness were used.

The final investigative question was to evaluate the acceptability of the proposed tri-service message as a replacement for the Type 1 messages currently in use.

Survey question 11 was designed to evaluate this variable of interest. The indicant used in designing this question was respondents' willingness to adopt the proposed tri-service message over that of their respective service.

Survey questions associated with demographics were structured to provide data concerning the grade, experience level, type of MTF, and frequency of contact with Type 1 messages among recipients. This data was not maintained by the service-level medical logistics offices and was determined by the researchers to be essential in the development of an effective tri-service Type 1 message.

Measurement Scales. With the exception of questions concerning demographic data, the survey consisted of quantitative scale questions. Likert Scales were selected due to their relative ease of development and utility in collecting ordinal data required for the comparison of response means among the population subgroups (12:220-221). Each of the Likert Scales were constructed as depicted in Table 1 below:

Table 1

An Example of Likert Scale Used in the Survey

Strongly	_	Neither Agree or disagree	Strongly	_
1	2	3	4	5

These scales provided respondents a five point range of values representing a continuum of differing degrees of opinion with respect to the survey question.

Instrument Testing. Content validity of the proposed mail survey questionnaire was assessed through pretesting of survey drafts among a small group of medical logistics personnel at Wright-Patterson Air Force Base. Pretesting of the survey instrument assisted the researchers in increasing response to the instrument through assessment of respondent interest. Survey content validity was improved through amendment of question meaning and sequencing, and refinement of the length and continuity of the survey (12:378-380). Pretesting also assisted in decreasing potential researcher bias expressed in construction of survey questions and instructions to survey respondents.

<u>Data Collection Plan</u>. A total design method was used to design and implement the survey (10:12). In such a method, the preparation and conduct of the mail survey are focused on maximizing participant response. Survey

techniques such as preliminary notification, sponsorship, restricted questionnaire length, and anonymity were used to improve the survey response rate (12:334-335).

As the accuracy of mail survey responses has been demonstrated to be related to both the respondent's perception of the source of a survey and the degree of anonymity present in survey completion, sponsorship and anonymity were two elements of the data collection plan which the researchers considered critical (11:183-184). Sponsorship was sought and gained by the researchers from the commanders of the Army, Navy, and Air Force medical logistics offices. These offices, though not in a command relationship with survey respondents, none the less maintain close communication and informational relationships. researchers obtained a preliminary notification memorandum from each of these commanders which stated that the research being conducted was sanctioned by the respective Army, Navy, and Air Force medical logistics offices. These preliminary notifications are enclosed in Appendix F, G, and H. In order to encourage both an increased survey response rate and candid responses, anonymity of respondents was maintained. Anonymity of respondents was ensured in the questionnaire instructions and reemphasized several times throughout the survey.

<u>Plan of Data Analysis</u>. As detailed above, the Likert Scales used collect ordinal data. Ordinal data allows the

performance of parametric statistical examination, specifically, the derivation of a sample grand mean, and further a mean within each of the population subgroups of the sample. The value of a grand mean and subpopulation mean were both of concern to the researchers. The population mean depicts the relative population attitude, along the Likert Scale presented, toward the specific survey question being answered. Subpopulation means are used to determine whether or not the mean responses of the various population subgroups differ significantly from each other with respect to the survey question being answered.

The One Way Analysis of Variance (ANOVA) procedure was selected to test the relationships which existed between mean responses of subgroups within the population. Stated in terms of hypothesis testing, the ANOVA procedure was utilized to investigate the following hypothesis:

- $H_0$ : There is no significant difference in the attitudes of the subpopulations with respect to the survey question being addressed ( $u_1 = u_2 = u_3$ ).
- H<sub>a</sub>: A significant difference exists between at least two of the subpopulation means.

Thus, if the observed value of "p" associated with a test of the null hypothesis is greater than the resultant table value at Alpha = .1, the null hypothesis can be rejected and the alternate hypothesis accepted. Simply, this would mean that the difference observed between the subgroup means is greater than that expected by chance. Thus, there is a statistically significant difference in the attitudes of the

population subgroups with respect to the survey question being answered.

The conduct of ANOVA required three significant assumptions on the part of the researchers. First, that the samples were selected randomly and independently from the respective subpopulations. Second, that all population probability distributions were normal. Finally, ANOVA procedures assume that the variances of the subpopulations being compared were equal (19:866).

As the sample subpopulations were selected through randomized design, the first assumption was met. In the second instance, the Central Limit Theorem states that due to the relatively large size of the sample of respondents, a normal distribution will be approximated. In order to assess variance of the subpopulations, a Bartlett's test for equality of variance was performed for each ANOVA comparison to test this assumption (23:252).

The ANOVA procedure will be used only to assess the relative agreement of means among population subgroups. The Likert Scales used in the survey do not lend themselves to any inference concerning the degree of difference between the values on the scale. For example, it can be inferred that a mean value of two is less than a mean value of three, however, the degree of differentiation between these two means cannot be determined. Degree of differentiation is

not a property of ordinal level data as collected in this survey.

Statistical Analysis Package. In conducting data analysis associated with the questionnaire, the STATISTIX statistical analysis software package, version 3.5, was used. STATISTIX is an interactive, integrated statistical analysis program for IBM type personal computers (1:1). Data were directly entered into the STATISTIX program. The ANOVA procedures described above were then conducted using the "One Way AOV" procedure (1:181).

# Research Design Limitations

Several assumptions were made in the conduct of this research. As detailed under investigative questions two and three above, it was assumed that respondents to both interviews and mail surveys would answer each question completely and accurately. A second assumption was that the non-responding portion of the survey population would not appreciably affect data collection and analysis of the data.

A limitation of this study rests in the ability to perceive, measure, and quantify the attitudes and perceptions of respondents. To the extent possible, the research design associated with each research question was structured to compensate for this limitation. A further limitation to this study was that investigation was not conducted into any potential relationships between the

variables of interest. The final limitation to the conduct of this research concerns the relative amount of time necessary to conduct mail surveys. As a consequence, the sample for the mail survey was restricted, to the extent possible, to MTFs within the continental United States. As overseas MTFs represent a relatively small proportion of the population which currently receives Type 1 messages, the exclusion of these activities was not anticipated to affect the ability to generalize the results of this survey to the population as a whole.

### Chapter Summary

This chapter described the research design employed in this study. Research question one was investigated using an observational study research method. A survey population and sample were identified, data collection methods were discussed, and a plan of data analysis was articulated.

In research question two, an iterative process of interviews was selected as the research method. Data collection and data analysis were conducted simultaneously, as the researchers developed and refined a streamlined notification process and a proposed tri-service Type 1 message for defective medical material.

A mail survey methodology was selected to investigate research question three. Stratified random sampling was conducted among two groupings of subpopulations. The ANOVA

procedure for investigation of variance among subpopulation means was proposed as the primary method of data analysis for this research question.

Chapter IV, Findings and Analysis, will present the analysis of the data generated by each research question.

# IV. Findings and Analysis

# Chapter Overview

This chapter provides an analysis of the data collected through personal interviews, observation, and survey. These research methods were conducted to address the three research questions presented in Chapter I: the efficiency of the current service-level notification process for Type 1 medical material complaints; the development of a streamlined process for notification of Type 1 medical material complaints; and, the effectiveness of a proposed, tri-service Type 1 message.

Observational studies were conducted at the Army, Navy, and Air Force medical logistics offices at Fort Detrick, Maryland. During these studies, a detailed examination of the notification process for defective medical materiel was conducted. In addition, data were collected concerning the resources required to accomplish each services' notification mission.

Personal interviews were conducted with the quality control supervisors of each service's medical logistics office. Questions regarding the procedures for a streamlined notification process for defective medical material and the format required of a tri-service Type 1 message were addressed. Through subsequent interviews, a

streamlined notification system was identified and a single tri-service Type 1 message was developed.

In order to assess the effectiveness of the proposed tri-service message, a mail survey was conducted of a sample group consisting of various MTFs from the three services.

The sample was further stratified to proportionally represent reserve, mobile, and fixed facility components of the three services.

This chapter will begin with an analysis of the efficiency of the current notification process (research question one). This will be followed by a brief discussion of the proposed streamlined notification process and the development of the tri-service message (research question two). Finally, the response rate and demographic data generated from the survey instrument will be discussed. This will be followed by an analysis of the effectiveness of the proposed tri-service message (research question three).

## Efficiency of the Current Notification Process

Research question one focuses on the efficiency of the existing notification process for Type 1 medical material complaints. This section provides an analysis of the resources consumed by the three services' medical logistics offices in the generation of Type 1 messages. These resources include processing time, personnel, and equipment required to receive feeder messages from the DPSC, prepare

subsequent service-specific Type 1 messages, and transmit the messages to their respective MTFs.

Investigative question one explores the length of time each medical logistics office takes to generate and transmit Type 1 messages. Through personal interviews and direct observation of the message generation process within the quality control sections of the services' medical logistics offices, it was found that each service processed their respective Type 1 messages using different time standards. These standards are shown in Table 2.

Table 2
Processing Times for Type 1 Messages

<u>Service</u>	Processing Time
Army	4 Hours
Navy	8-72 Hours
Air Force	4-8 Hours

Through investigation of historical records, it was determined that the services continually meet their respective processing time standards for Type 1 messages. As noted above, however, each of the services operate under different time standards. Consistency among the three services is not demonstrated in these varying standards.

Investigative question two explores the personnel resources required by the medical logistics offices of the three services to process Type 1 messages for defective medical material. Personal interviews and direct observation revealed that the quality control section of each of the three service-level medical logistics offices were comprised of different numbers of personnel of varying grades. The personnel resources required to transmit these messages are depicted in Table 3.

Table 3

Personnel Required for Type 1 Message Transmission

		·	
Service	Personnel Requirement	Qty	
Army	GS-7 supply techs	3	
	GS-11 supervisor	1	
•	E-5 supply clerk	1	
<u>Navy</u>	GS-7 supply tech	1	
	0-4 supervisor	1	
Air Force	GS-7 supply techs	2	
	GS-11 clinincal engineer	1	
	E-8 supervisor	1	

Investigative question three explores the equipment required to transmit the current Type 1 messages for defective medical materiel at the medical logistics offices of each service. Through personal interviews, it was determined that the use and distribution of equipment within the three medical logistics offices would not be an efficiency factor. Though similar equipment is found among each of the services' quality control sections, the respondents indicated that existing equipment used to generate, transmit, and file Type 1 messages would remain at their respective offices for use in other functions should the message generation mission be shifted to another agency. The equipment required to prepare Type 1 messages consists mainly of personal computers and other common items of office equipment.

The first research question focuses on the efficiency of the current notification process for Type 1 medical materiel complaints. Efficiency, by definition, is the act of being productive without waste (20:362). Analysis of the three investigative questions related to this research question reveals the duplication of effort taking place at the three services' medical logistics offices with respect to the generation of Type 1 messages. The time, effort, and manpower required to generate essentially the same Type 1 message is multiplied threefold due to the redundancies of the current process. In addition, separate historical

databases for Type 1 messages have been established and are being maintained by each of the medical logistics offices. Furthermore, the costs for transmitting Type 1 messages through the Fort Detrick Message Center is amplified three times due to the supposed "uniqueness" of each services' Type 1 message.

What is unique about these messages is the address indicator group heading at the top of each message and the point of contact line for each of the respective services. But for these minor exceptions, the body of the Army, Navy, and Air Force Type 1 messages are essentially the same. These factors of inefficiency and duplication of resources and effort led to the development of a proposal for streamlining the current notification process and a triservice message for defective medical material which are discussed in the next section.

### Development of a Streamlined Notification Process

The second research question explores the development of a streamlined notification process for defective medical materiel within the DoD. Through a series of iterative personal interviews, the researchers developed a tri-service notification system for Type 1 complaints. A component fixture of this notification system is a tri-service message for defective medical materiel which the researchers have developed for Type 1 complaints.

Investigative question one focuses on the development of a tri-service notification system for defective medical materiel. In creating a tri-service notification system, the researchers sought to eliminate the duplication of functions and resources which currently exist among the notification systems within the services' medical logistics offices.

In conducting interviews associated with this investigative question, the researchers identified several essential characteristics which were required of a triservice notification system. Each of the personal interview respondents echoed the need for the proposed system to be as fast as possible in communicating the required information to MTFs. With this essential characteristic identified, the researchers have developed a notification process to receive the DPSC feeder message and develop the subsequent triservice Type 1 message within 4 hours. In this respect, the proposed system of notification models the current Army notification process, which is the fastest of the three services.

The second essential characteristic expressed by each of the survey respondents during the personal interviews pertained to the staffing of the proposed tri-service notification activity. Interview respondents strongly articulated a requirement that the activity be staffed with a requisite number of personnel possessing the appropriate

grade levels commensurate with the critical, lifethreatening importance of the Type 1 notification function.

The need for accuracy was voiced on many fronts.

Interview respondents maintained that both the joint address indicator group and the historical data files associated with the tri-service messages be as accurate as possible. It was agreed that of each of the service-level medical logistics offices would be responsible for providing the tri-service message generating activity with the address indicator groups associated with their respective MTFs. The service-level medical logistics offices would also be responsible for updating their respective address indicator groups. It was further agreed that each service's medical logistics office would have on-line access to the historical database which would be maintained by the tri-service message generation activity.

Investigative question two explores the development of a single tri-service Type 1 message for defective medical materiel. As with the proposed tri-service notification system, a consensus building approach was taken by the researchers.

Through an iterative interview process, the essential characteristics of the proposed tri-service message were identified. Concerns of the interview respondents centered on the format, clarity, completeness, and acceptability of the proposed message by the MTFs of their respective

services. Over the course of successive interviews, adjustments were made to the format and content of the proposed message such that its final form reflected the essential characteristics articulated by the respondents. The proposed tri-service message is enclosed as Appendix E to this study.

During the development of the proposed tri-service message, there was one issue that interview respondents could not reach a consensus on. This issue was the single activity "point of contact" for recipient MTFs should subsequent information related to the defective medical item be required. Each of the services expressed the need and importance of maintaining the point of contact function within their respective quality control sections. A compromise was reached in the final message format in which a service point of contact line appears for each of the medical logistics offices.

## Analysis of the Tri-Service Message

In order to assess the effectiveness of the proposed tri-service message for defective medical material, a mail-survey was conducted of a stratified random sample composed of Army, Navy, and Air Force MTFs and their respective reserve, mobile, and fixed components. The construct of the survey instrument emphasized respondent evaluation of the variables of interest which were identified by the

researchers; message clarity, understanding, completeness, format, and acceptability. The following section analyzes the survey response and demographics of the respondents.

Survey Response. The survey questionnaire was mailed to 199 MTFs; 75 Army activities, 58 Navy activities, and 66 Air Force activities. The population was further stratified by component into reserve facilities, mobile facilities, and fixed facilities. In total, 89 activities responded to the survey which resulted in an overall response rate of 44.7%. Details regarding the responses from the three services and their respective components are listed in Table 4.

Table 4
Survey Response Rate by Sample Group

	Group	Surveys Mailed	Surveys Received	Response Rate
Army	reserve component	25	11	44.0%
Army	mobile facilities	25	10	40.0%
Army	fixed facilities	25	13	52.0%
Navy	reserve component	25	10	40.0%
Navy	mobile facilities	8	3	37.5%
Navy	fixed facilities	25	14	56.0%

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Table 4 (continued)
Survey Response Rate by Sample Group

Group	Surveys Mailed	Surveys Received	Response Rate
Air Force reserve component	25	10	40.0%
Air Force mobile facilities	16	6	37.5%
Air Force fixed facilities	25	12	48.0%
<u>Total</u>	199	89	44.7%

Demographic Statistics. Several survey questions were designed to collect information concerning the essential demographic characteristics of the respondents. The following statistics provide a detailed view of these characteristics, both between and among the services. The respondents' experience with Type 1 messages is the first characteristic analyzed. Respondents had varying years of experience, ranging from a low of one year to a high of 30 years. The results are summarized in Table 5.

Table 5
Number of Years Experience with Type 1 Messages

Group	Average Years of Experience
Army mobile facilities	5.2
Army fixed facilities	6.9
Navy reserve component	7.2
Navy mobile facilities	2.7
Navy fixed facilities	6.9
Air Force reserve component	7.5
Air Force mobile facilities	11.2
Air Force fixed facilities	9.2

The next survey question provides specific information concerning the type of MTF to which the respondent belonged. The MTFs to which respondents were assigned displayed the spectrum of medical activities in existence in the military today; Army medical detachments, Navy aircraft carriers, Air Force clinics, a variety of fixed hospitals, and so on. A summary of the results is presented in Table 6.

Table 6

Type of Medical Treatment Facility

Type of Medical Facility	Number of Respondents
Medical Group	1
Medical Detachment	8
Medical Battalion	3
60-bed Mobile Hospital	3
400-bed Mobile Hospital	6
100 to 200-bed Fixed Hospital	11
200 to 300-bed Fixed Hospital	24
300 to 400-bed Fixed Hospital	4
Naval Reserve Center	10
Aircraft Carrier	3
Aeromedical Evacuation Facility	1
USAF Clinic	2
TAC Clinic	5
TAC Hospital	2
Contingency Hospital	6

The next demographic question queried respondents for their military or civilian grade. Again, a wide spectrum is evidenced among the enlisted members, officers, and civilian personnel who responded to the survey. Of the 89 total respondents, 41 were enlisted members, 38 were officers, and 10 were civilians. The major groups within each category that responded were E-6s and E-7s, O-3s and O-4s, and GS-5s

and GS-6s. Table 7 summarizes the data reflecting the grades of respondents.

Table 7
Grades of Respondents

Grade	Number of Respondents
E-4 & E-5	15
E-6 & E-7	23
E-8 & E-9	3
WO1 & WO2	1
0-1 & 0-2	8
0-3 & 0-4	27
0-5 & 0-6	2
GS-5 & GS-6	7
GS-7 & GS-9	3

The final demographic question explores the frequency with which respondents managed actions concerning Type 1 messages. The majority of respondents managed actions concerning Type 1 messages on a frequent or intermittent basis. The data are summarized in Table 8.

Table 8
Frequency of Managing Type 1 Messages

Frequency	Number of Respondents
Frequent	61
Intermittent	22
Not At All	6

## Effectiveness of the Proposed Tri-Service Type 1 Message

The third research question posed in this study focuses on the effectiveness of the proposed tri-service Type 1 message for defective medical material. Six specific investigative questions were developed to examine the clarity, understanding, completeness, format, and acceptability of the proposed tri-service message. The data, analysis, and findings associated with each of these investigative questions are presented in this section.

Explanation of Analysis of Variance Results. As the Analysis of Variance (ANOVA) procedure will be used throughout this chapter to analyze the mail survey data, an explanation of the significance of the ANOVA and the specific table format found throughout this study follows. The data presented in Table 9, representing the analysis of survey question 1, will be referenced for this explanation.

Question 1 was included on the survey to determine if respondents at MTFs were able to recognize the new message

format as a Type 1 message for defective medical materiel.

The term "service average" reflects the average Likert Scale response to the question by all components of that service.

For example, the Army service average of 4.32 in Table 9 represents the average response given by all Army Reserve,

Army mobile, and Army fixed MTFs to survey question 1.

The "p-value" is an indication of the significance of the difference between the means of the population subgroups, in this instance, Army, Navy, and Air Force, that are being analyzed. Values greater than .1000 indicate a level of confidence of 90% or greater in the results. For example, the p-value of .3701 in Table 9 indicates that when evaluated at the 90% confidence level, there is not a significant difference between the average responses given by the Army, Navy, and Air Force respondents to survey question 1.

The term "component average" reflects the average

Likert Scale response to the question by all services within that component. For example, the reserve component average of 4.16 in Table 9 represents the average response given by all Army Reserve, Navy Reserve, and Air Force Reserve respondents to survey question 1.

The "p-value" is an indication of the significance of the difference between the means of the population subgroups being analyzed, in this instance, reserve, mobile, and fixed MTFs. Values greater than .1000 indicate a level of

confidence of 90% or greater in the results. For example, the p-value of .2054 in Table 9 indicates that when evaluated at the 90% confidence level, there is not a significant difference between the average responses given by the reserve, mobile, and fixed MTF respondents to survey question 1.

The term "total average response" is the average Likert Scale response of all 89 respondents to question 1 on the survey. This number can be interpreted as a grand mean, or sample mean. In this instance, an average response of 4.30 indicates that the typical survey respondent agreed that the intent of the proposed tri-service message was clear. ANOVA reveals that differences in mean responses to survey question 1 among the three services and among the components were not statistically significant at the 90% confidence level.

The Tables which follow present a summarized version of the ANOVA output, as generated by STATISTIX, for each mail survey question. For a more detailed presentation of both the specific data set used and ANOVA results generated for each survey question, the reader is directed to Appendix I of this study.

Clarity of the Tri-Service Message. The first investigative question pertains to the clarity of the proposed tri-service Type 1 message. The researchers were interested in assessing the respondents' ability to

determine the intent of the message and the actions required of them in response to the information contained in the message. Survey questions 1 and 2 were designed to answer this investigative question. The results from each question are presented in Tables 9 and 10 below.

In summary, ANOVA reveals that the difference in the mean responses to survey question 1 among the three services or among their reserve, mobile, and fixed components, was not significant at the 9-% confidence level. In this instance, the average Likert Scale response of 4.30 indicates that the typical survey respondent agreed that the intent of the proposed tri-service message was clear. A summary of the data is detailed in Table 9.

Table 9
Survey Responses to Question 1

Survey Question 1. The intent of the tri-service Type 1 medical material message is clear.

Group	Average Response	p-value	Total Average Response
Service			
Army	4.32		
Navy Air Force	4.18 4.39		
		.3701	

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Table 9 (continued)
Survey Responses to Question 1

			<del></del>
Group	Average Response	p-value	Total Average Response
Component			
Reserves	4.16		
Mobile	4.37		
Fixed	4.39		
		. 2054	
	,		4.30

Survey question 2 asks respondents whether the actions required of them in the tri-service message are clear. Type 1 messages are normally issued when there is confirmation of a defective item (supply or equipment) whose use could result in death or serious injury. Actions required on the part of logistics personnel at MTFs are normally to suspend the defective item from active stock and recall any previously issued stock which is suspect. It is for this reason that the actions required of respondents, as stated in the message, must be clear to them.

ANOVA reveals that the difference in the mean responses to survey question 2 among the three services, or among their reserve, mobile, and fixed components, was not statistically significant at the 90% confidence level. In this instance, the average Likert Scale response of 4.30 indicates that the typical survey respondent agreed that the

actions required of them in the proposed tri-service message were clear. A summary of the data is detailed in Table 10.

Table 10
Survey Responses to Question 2

Survey Question 2. The actions required of me in this message are clear.

Group	Average Response	p-value	Total Average Response
Service			
Army	4.18		
Navy	4.30		
Air Force	4.46		
		.2890	
Component			
Reserves	4.10	•	
Mobile	4.47		
Fixed	4.39		
		.1207	
			4.30

Ability to Understand the Tri-Service Message. The second investigative question relating to the effectiveness of the proposed tri-service Type 1 message concerns the ability of the recipient to understand the message. Survey questions 3 and 11 were designed to answer this investigative question. The results from each question are presented in Tables 11 and 12 below.

Question 3 was included on the survey to determine if respondents could identify their respective services' portion of the survey, and if the actions found there were easily understood by them. One concern expressed during the development of the tri-service message was whether personnel from one service might be confused by the addition of another services' information on the same message. For Type 1 messages to be effective, it is imperative that the recipients from all services be able to quickly locate and understand all information on the message which pertain to their respective service.

ANOVA reveals that the difference in the mean responses to survey question 3 among the three services, or among their reserve, mobile, and fixed components, was not statistically significant at the 90% confidence level. In this instance, the average Likert Scale response of 4.29 indicates that the typical survey respondent agreed that the service-specific actions detailed on the proposed triservice message were easy to understand. A summary of the data is detailed in Table 11.

Table 11
Survey Responses to Question 3

Survey Question 3. I find the actions specific to my branch of service easy to understand.

Group	Average Response	p-value	Total Average Response
Service			
Army Navy Air Force	4.22 4.22 4.43	. 4784	
Component			
Reserves Mobile Fixed	4.11 4.42 4.36	. 2580	4.29

Question 11 was included on the survey to determine if respondents found any portion of the tri-service message confusing. Any confusion concerning Type 1 messages on the part of logistics personnel at MTFs could result in the issuance of defective medical material. Therefore, respondents from all services and components must not be confused by any portion of the message. The average response of all units was 1.90. (A low score represents disagreement with question 11.)

ANOVA reveals that the difference in the mean responses to survey question 11 among the three services, or among

their reserve, mobile, and fixed components, was not statistically significant at the 90% confidence level. In this instance, the average Likert Scale response of 1.90 indicates agreement among respondents that the tri-service message is not confusing to them. A summary of the data is detailed in Table 12.

Table 12
Survey Responses to Question 11

Survey Question 11. I find certain aspects of the tri-service Type 1 defective medical material message confusing.

confusing.		Total
Average Response	p-value	Average Response
2.03 1.82 e 1.82	.4317	
1.87 2.00 1.87	.8027	1.90
	2.03 1.82 1.82	Average Response  2.03 1.82 1.82 1.87 2.00 1.87

<u>Completeness of the Tri-Service Message</u>. Investigative question three pertains to the completeness of the information contained in the tri-service message. Survey

question 4 was designed to answer this investigative question.

Question 4 was included on the survey to determine if the information regarding the defective medical material contained on the message was complete. During the development of the tri-service message, interview respondents from the medical logistics offices of the three services agreed that recipients at MTFs should receive all of the information necessary to take required actions. Many recipients of Type 1 messages are deployed or located in geographically remote regions which have limited communications. Therefore, it is essential that the Type 1 messages reaching recipients provide them all of the information required to perform the actions directed on the suspect medical material. It is for this reason that complete information concerning the defective medical material within the Type 1 message is essential.

ANOVA reveals that the difference in the mean responses to survey question 4 among the three services, or among their reserve, mobile, and fixed components, was not statistically significant at the 90% confidence level. In this instance, the average Likert Scale response of 4.10 indicates that the typical survey respondent agreed that the information contained in the proposed tri-service message was complete. A summary of the data is detailed in Table 13.

Table 13
Survey Responses to Question 4

Survey Question 4. I find the information in the tri-service Type 1 defective medical material message complete.

_	Average		Total Average
Group	Response	p-value	Response
Service			
Army	4.16		
Navy	4.00		
Air Force	4.11		
		.6836	
Component			
Reserves	3.95		
Mobile	4.16		
Fixed	4.18	•	
		.3810	
		•	4.10

The Format of the Tri-Service Message. Investigative question four pertains to the format of the tri-service message. To ensure recognition of the Type 1 message, recipients at the MTFs must identify the format of the message as that of a Type 1. Survey questions 5 and 6 were designed to answer this investigative question.

Question 5 was included on the survey to determine if respondents understood the format of the tri-service message. The format of the proposed tri-service message is different from the format of the messages that the Army,

Navy, and Air Force currently use in that there are new address indicator groups, some service-unique actions, different service points of contact, and so on. In the development of the tri-service message, it was important that the new format minimize the confusion on the part of logistics personnel at the receiving MTFs.

ANOVA reveals that the difference in the mean responses to survey question 5 among the three services, or among their reserve, mobile, and fixed components, was not statistically significant at the 90% confidence level. In this instance, the average Likert Scale response of 4.32 indicates that the typical survey respondent agreed that the format of the proposed tri-service message is understandable. A summary of the data is detailed in Table 14.

Table 14
Survey Responses to Question 5

Survey Question 5. The format of the tri-service defective medical material message is easy to understand.

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Table 14 (continued)
Survey Responses to Question 5

Group	Average Response	p-value	Total Average Response
Service			
Army	4.35		
Navy	4.22		
Air Force	4.36		
		.6714	
Component			
Reserves	4.23		
Mobile	4.42		
Fixed	4.33		
		.5639	
		•	4.32

Question 6 also pertains to the format of the proposed tri-service message. At times, message recipients may require additional information concerning the contents of the Type 1 message. It was for this reason that interview respondents felt it critical that each service maintain a distinct point of contact for Type 1 messages and that this information appear as a separate line on each message.

Conversely, the content of some Type 1 messages require personnel at MTFs to contact their respective service's medical logistics office. Should these actions be required, it is essential that logistics personnel recognize their service point of contact as it is detailed in the message.

ANOVA reveals that the difference in the mean responses to survey question 6 among the three services, or among their reserve, mobile, and fixed components, was not statistically significant at the 90% confidence level. In this instance, the average Likert Scale response of 4.37 indicates that the typical survey respondent agreed that they are able to identify their respective service point of contact on the proposed tri-service message. A summary of the data is detailed in Table 15.

Table 15
Survey Responses to Question 6

Survey Question 6. I can easily identify my branch or service point of contact if clarification of the tri-service Type 1 defective medical material message is required.

	Average		Total Average
Group	Response	p-value	Response
Service			
Army	4.35		
Navy	4.30		
Air Force	4.46		
		.6264	
Component			
Reserves	4.36		
Mobile	4.42		
Fixed	4.36		
		.9222	
			4.37

Comparison of Effectiveness for Both Messages.

Investigative question five compares the effectiveness of the proposed tri-service message to the effectiveness of the current Type 1 message used in each service. Survey questions 7, 8, and 9 were designed to answer this investigative question.

Question 7 was included on the survey to determine if respondents found the intent of the proposed tri-service message to be clearer than the current Type 1 message in use by their respective service. In this question, a higher numbered response indicates stronger agreement with the statement that the intent of the tri-service message is clearer than the intent of the messages currently used to communicate Type 1 complaints. In contrast, a lower numbered response would indicate that the respondent finds the intent of their respective services' current Type 1 message clearer.

ANOVA reveals that the difference in the mean responses to survey question 7 among the three services, or among their reserve, mobile, and fixed components, was not statistically significant at the 90% confidence level. In this instance, the average Likert Scale response of 3.48 indicates that the typical survey respondent found the intent of the proposed tri-service message to be clearer than the intent of the Type 1 messages currently used by

their respective service. A summary of the data is detailed in Table 16.

Table 16
Survey Responses to Question 7

Survey Question 7. The intent of the tri-service Type 1 defective medical material message is clearer to me than the intent of Type 1 messages currently in use by my branch of service.

Group	Average		Total Average
	Response	p-value	Response
Service		•	•
Army	3.65	·	
Navy	3.41		
Air Force	3.34		
		.2496	
Component			
Reserves	3.69		
Mobile	3.42		
Fixed	3.33		
		.1382	
			3.48

Question 8 was included on the survey to determine if respondents perceived a difference in clarity of required actions between the tri-service message and the Type 1 message currently used by their respective service.

Respondents were asked to compare the messages with respect to the clarity in the communication of actions required of them. In this question, a higher numbered response

indicates stronger agreement with the statement that the actions required of the recipient in the tri-service message are clearer than that of the messages currently used to communicate Type 1 complaints. In contrast, a lower numbered response would indicate that the respondent favors their respective services' current Type 1 messages.

ANOVA reveals that the difference in the mean responses to survey question 8 among the three services, or among their reserve, mobile, and fixed components, was not statistically significant at the 90% confidence level. In this instance, the average Likert Scale response of 3.53 indicates that the typical survey respondent found the actions required in the tri-service message to be slightly clearer than those in the Type 1 messages currently used by their respective service. A summary of the data is detailed in Table 17.

Table 17
Survey Responses to Question 8

Survey Question 8. The actions required of me in the tri-service Type 1 defective medical materiel message are clearer than the Type 1 messages currently in use by my branch of service.

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